

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/830,037 04/20/01 DOW

G PU3556USW

023347 HM22/0718
DAVID J LEVY, VP INTELLECTUAL PROPERTY
GLAXO WELLCOME INC
GLOBAL INTELLECTUAL PROPERTY
FIVE MOORE DR, PO BOX 13398
RESEARCH TRIANGLE PARK NC 27709-3398

EXAMINER

HUI, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/830,037

Applicant(s)

DOW ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14, 15, 19, 20, 23, and 24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 15 provide for the use of the instant lotion, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The term "AUC" recited in claims 19 and 23 render the claims indefinite because it is unclear what AUC refers to. Does it refer to relative AUC or absolute AUC?

Claims 23 and 24 recite the limitation "The topical lotion" in line 1. There is insufficient antecedent basis for this limitation in the claim. Please note that the base claim, claim 21, is drawn to a method of treatment.

The expression "chemically and physically stable" in claims 20 and 24 is a relative term which renders the claim indefinite. The expression "chemically and physically stable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The expression renders the claims indefinite as to the degree of stability of the lotion referred to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 16, 18, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill (WO 92/14472 from the Information Disclosure Statement received April 20, 2001).

Hill teaches a topical composition employing 0.05% of fluticasone propionate, 10.00% of cetostearyl alcohol, 10% of White Soft Paraffin, 2.50% of Polysorbate 60, 10.00% of polypropylene glycol, and purified water (see particular Example 1). Hill also teaches that the topical composition is prepared by mixing the ingredients and melting

Art Unit: 1617

the mixture and then cool the mixture down (See particular page 2, third paragraph).

Hill also teaches that the topical composition is useful in treating skin conditions

including inflammation (See particular page 1, 6th paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 6-15, 17, 19, 20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill (WO 92/14472 from the Information Disclosure Statement received April 20, 2001) and Gordon (Clinical therapeutics, 1998;20(1):26-39) in view of Richards (US Patent 4,985,418).

Hill teaches a topical composition employing 0.05% of the corticosteroid, fluticasone propionate, 10.00% of cetostearyl alcohol, 10% of White Soft Paraffin, 2.50% of Polysorbate 60, 10.00% of propylene glycol, and purified water (see particularly Example 1). Hill also teaches that the topical composition is prepared by mixing the ingredients and melting the mixture and then cool the mixture down (See particularly page 2, third paragraph). Hill also teaches that the topical composition is useful in treating skin conditions including inflammation (See particularly page 1, 6th paragraph).

Gordon teaches a corticosteroid containing composition employing Cetostearyl alcohol, cetomacrogol 1000, Isopropyl myristate, propylene glycol. Dimethicone 360, citric acid, sodium citrate, imidurea, and water (see page 28, table 1).

The references do not expressly teach the employment of methyl paraben and propyl paraben in the lotion. The references do not expressly teach the preparation of the topical composition employing mixing the ingredients at an elevated temperature and then heat the mixture. The references do not expressly teach the viscosity of the topical compositions to be 2,000 to 17,000 cps or 3000 to 13,000 cps. Both references do not expressly teach the blanching score and the AUC of the lotion.

Richards teaches that methyl paraben and propyl paraben are excipients known to be useful in a fluticasone topical composition (See particular col. 5, lines 20-30). Richards also teaches the preparation of the fluticasone composition involving the process of mixing the ingredients at 70 degree Celsius and then heating the mixture to 70 degree (See particular col. 6, line 10-17).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to formulate a topical fluticasone composition with the ingredients herein. It would have also been obvious for one of ordinary skill in the art at the time the invention was made to prepare a topical fluticasone composition that has the viscosity herein and the blanching score and AUC herein. It would have also been obvious for one of ordinary skill in the art at the time the invention was made to prepare a topical fluticasone composition by mixing the ingredients at an elevated temperature and then heating up the mixture.

One of ordinary skill in the art would have been motivated to formulate a topical fluticasone composition with the excipient ingredients herein because the ingredients herein are known to be useful in formulating topical corticosteroid compositions. Therefore, incorporating all the ingredients herein with any known active corticosteroid compounds including fluticasone would have been reasonably expected to be useful in preparing the topical corticosteroid composition herein.

One of ordinary skill in the art would have been motivated to prepare a topical fluticasone composition that has the viscosity herein and the blanching score and AUC herein because the optimization of result effect parameters (e.g., viscosity, blanching score and AUC) is obvious as being within the skill of the artisan.

Based on Richards, heating up and mixing the ingredients herein in the method of preparing the topical fluticasone composition is obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

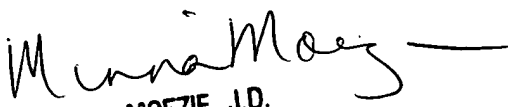
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Application/Control Number: 09/830,037
Art Unit: 1617

Page 7

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
July 16, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600